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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/213,834	12/17/98	ROMANTCHIKOV	Y 99999/400400

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HM22/1130

EXAMINER

SIU, S

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

11/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/213,834

Applicant(s)

ROMANTCHIKOV, YURI (KOURI)

Examiner

Stephen C Siu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30, 33-38 and 40-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-22, 24-30, 33-36, 42-53, 55, 56, 58, 59, 62, 65 and 66 is/are allowed.
- 6) ☒ Claim(s) 23, 37, 38, 40, 41, 54, 60, 61, 63 and 64 is/are rejected.
- 7) ☒ Claim(s) 57 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *See Continuation Sheet*.

Continuation of 20. Other: Notice to comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

### **DETAILED ACTION**

This Action is in response to Applicant's amendment received September 14, 2000 (paper number 4).

The objection to claims 17 and 23 as cited in the Office Action mailed March 13, 2000 (paper number 2) is withdrawn in view of Applicant's amendments and arguments.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph as cited in the Office Action mailed March 13, 2000 (paper number 2) is withdrawn in view of Applicant's amendments and arguments.

The rejection of claims 31 and 32 under 35 U.S.C. 102(e) as being anticipated by Guegler as cited in the Office Action mailed March 13, 2000 (paper number 2) is withdrawn in view of Applicant's amendments and cancellation of these claims.

The rejection of claims 31-34 and 37-39 under 35 U.S.C. 102(b) as being anticipated by Miki in light of Maniatis as cited in the Office Action mailed March 13, 2000 (paper number 2) is withdrawn in view of Applicant's amendments and arguments.

The rejection of claims 33-40 under 35 U.S.C. 103(a) over Miki in view of Aslanidis as cited in the Office Action mailed March 13, 2000 (paper number 2) is withdrawn in view of Applicant's amendments and arguments.

### ***Specification***

The disclosure is objected to because of the following informalities: the specification contains sequences that do not comply with sequence rules. In particular, sequences without identifying SEQ ID NOs are noted on pages 32, 33, 35, 36, 38, 39, 40, 42, 43, and 44. Amendment of the specification, substitute computer readable form

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copy of the "Sequence Listing", substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d) are required. See attached Notice to Comply with Requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Appropriate correction is required.

### ***Claim Objections***

Claim 57 is objected to because of the following informalities: the period is missing. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter as cited in the office action mailed March 13, 2000 (paper number 2) is maintained.

Claim 23 as amended recites a concentration comprising about  $10^{-21}$  to  $10^{-14}$  moles of nucleic acid fragment per 1 – 10,000 microliters which is confusing because it is not clear what the precise concentration is with the recitation of a range of microliters and a range of moles.

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Claims 37, 38, 40, 41, 54, 60 and 61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-38 and 40-41 recite "upon hybridization, ligase does not substantially covalently join said cohesive circularization ends" and claims 54, 60, and 61 recite "upon hybridization are not substantially covalently joined by ligase". This is indefinite because it is not clear what is meant with the use of the phrase "does not substantially" or "are not substantially". In particular, it is not clear if the claims are intended to recite that ligase is simply not present and therefore does not join the ends (but still capable of doing so if used) or if ligase, even if present, is not capable (i.e. "cannot") join the cohesive ends, for example in the presence of gaps. Further, with use of the word "substantially", it is not clear if ligase cannot and does not join the ends at all or if ligase joins the ends (i.e. "can") but does so to a lesser degree than expected. The metes and bounds of the claims are therefore unclear and the claims are indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Shizuya (Proc Natl Acad Sci, Vol.89, pages 8794-8797, September 1992).

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Shizuya teaches a cDNA library with a size distribution of the inserts ranging from 10 to 215 kb with an average size of 100kb. Restriction patterns of DNA were taken before and after culture and the sizes of the restriction fragments produced were compared with the originals. No visible difference between the two samples were observed (i.e., no substantial size bias). Page 8795, col.2 – page 8796, "Analysis of Human Inserts".

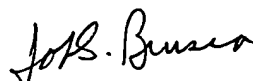
### ***Conclusion***

Claims 23, 37, 38, 40, 41, 54, 60, 61, 63 and 64 are rejected. Claim 57 is objected to. Claims 1-22, 24-30, 33-36, 42-53, 55, 56, 58, 59, 62, 65 and 66 are allowable.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu

  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER